UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

BLUEWILLOW BIOLOGICS, INC.,

Defendants.

Case No. 2:21-cv-10312

Hon. Stephen J. Murphy, III

AMENDED COMPLAINT

NOW COMES Plaintiff, TRUTEK CORP., by and through their attorneys, Law Office of Stanley H. Kremen, Esq. and The Law Office of Keith Altman, and for their Amended Complaint, hereby states the following:

PARTIES

1. Plaintiff, TRUTEK CORP. ("TRUTEK") is a corporation of the State of New Jersey, with principal offices at 281 East Main Street, Somerville, New Jersey, 08876.
2. Upon information and belief, Defendant, BlueWillow Biologics, Inc. ("BLUEWILLOW") is a corporation of the State of Delaware, with a place of business at 2311 Green Road, Suite A, Ann Arbor, Michigan 48105.

FEDERAL SUBJECT MATTER JURISDICTION

3. The subject matter jurisdiction of this Court arises under 28 U.S.C. § 1331

concerning a federal question, the Patent Laws of the United States, 28 U.S.C. §§ 1338(a), (b), and 35 U.S.C. § 271.

IN PERSONAM JURISDICTION

4. The *in personam* jurisdiction of this Court over Defendant BLUEWILLOW is proper under 28 U.S.C. § 1400(b) because the tort of patent infringement occurred in Michigan and BLUEWILLOW has an established place of business in Michigan.

VENUE

5. The venue of this Court is proper under the Patent Venue Statute, 28 U.S.C. § 1400(b) since the tort of patent infringement occurred within the State of Michigan, and Defendant BLUEWILLOW has an established place of business thereat, and which is furthermore located within the venue of the Eastern District of Michigan.

STATEMENT OF FACTS AND CAUSES OF ACTION

6. Ashok Wahi ("WAHI") is Chief Science an IP Officer of Plaintiff TRUTEK.
7. On November 21, 1995, United States Patent No. 5,468,488 (hereinafter the '488 Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Nasal Application Product and Method." The '488 Patent was assigned to TRUTEK.
8. On October 7, 1997, United States Patent No. 5,674,481 (hereinafter the '481 Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Nasal Topical Application Product." The '481 Patent was assigned to TRUTEK.

9. On January 18, 2005, United States Patent No. 6,844,005 (hereinafter the '005 Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Nasal Application Product With Increased Strength." The '005 Patent was assigned to TRUTEK.

10. On April 24, 2012, United States Patent No. 8,163,802 (hereinafter the '802 Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Multi-Acting Nasal Application Product, and Method," on a patent application that was filed at the United States Patent and Trademark Office (USPTO) on May 16, 2009. The '802 Patent was assigned to TRUTEK. The '802 Patent is attached hereto as Exhibit 6.

11. The patented technology made it possible for people to apply TRUTEK's manufactured products in and around their nasal passages to reduce reactions to airborne allergens and to reduce or eliminate reactions to viral infections from influenza and the common cold by restricting and inactivating virus sized particles. This is done by establishing an electrostatic charge in and around nasal passages.

12. As of the year 1992 going forward, TRUTEK utilized its patented and proprietary trade secret technology to establish proof of concept, develop, formulate, manufacture, sell, and/or license over-the-counter products under the brand name NasalGuard® AllergieBlock®, NasalGuard Cold&Flu Block®, NasalGuard® Multi Acting™, Anti-Stat Enhanced Mask™, NasalGuard Wipes™, NasalGuard Allergie Wipes™, NasalGuard Cold & Flu Wipes™, Skin and Hair super conditioners, Truteks® Skin and Truteks® skin care products, along with electrostatically charged nasal multipurpose products, nasal application (anti-stat) diagnostic products and, associated Technologies and Methodologies, Patents and Pending Patent Applications, also including

products under the brand names Chloraseptic Allergen Block and Little Allergies Allergen Block, Eisai Crystal Veil, Eisai Crystal Veil Cool, Nitto Nuru Mask, Nitto NasalGuard, further including but not limited to nasal application product lines such as gels, pre-moistened products for *e.g.* applicators, swabs, wipes, etc., sticks, nasal sprays, nasal washes, surgical masks, and multi-acting/integrated products.

13. Claim 1 of the '802 Patent claims a method of applying a formulation to the skin or tissue of a person's nasal passages in a thin film. The formulation electrostatically attracts and holds particulate matter to the thin film, and binds it to the thin film. The bound particulate matter is then inactivated by at least one ingredient that renders it harmless. One such claimed inactivating ingredient is benzalkonium chloride (claim 7). This process is sometimes referred to as "catch, hold, and kill."

BLUEWILLLOW'S Nanobio® Protect Products

14. According to information and belief, sometime in 2020, Defendant BLUEWILLOW manufactured and marketed one or more over-the-counter pharmaceutical products named NanoBio® Protect ("NANOBIO"). According to information and belief, the NANOBIO products were sold over-the-counter at least at CVS pharmacies nationwide, and were sold online to customers by Amazon.com.

15. BLUEWILLOW's website advertised the NANOBIO product being applied to a customer's nasal passages. Their product forms positively charged "NanoBio Droplets" that are approximately 600 nanometers[1] in size, which adhere to nasal membranes. Most harmful particles, such as bacteria or

[1] A nanometer is a billionth of a meter.

viruses (referred to as "germs"), are negatively charged. The positively charged "NanoBio Droplets" attract and bind to these particles. The NANOBIO product formulation contains benzalkonium chloride (which the website calls BZK) that adheres to the surface of the "NanoBio droplets." According to the website, the "NanoBio droplets" surround the germs and "kill them via membrane disruption." (See Exhibit 1 attached hereto.) The NANOBIO product implements the methodology of "catch, hold, and kill." The NANOBIO website "Frequently Asked Questions" section (Exhibit 2) describing the product further enforces this mechanism of action.

16. Sometime in 2020, WAHI suspected that the NANOBIO product infringes one or more of TRUTEK's patents. To that end, on June 23, 2020, TRUTEK personnel purchased the NANOBIO product from Amazon.com. After extensive in-house experimentation, it was indicated that the NANOBIO product functions by producing an electrostatic charge in and around the user's nasal passages. It was indicated that NANOBIO product infringes claims of TRUTEK's '802 Patent. On January 14, 2021, TRUTEK personnel purchased a NANOBIO product from CVS, and obtained similar results through in-house experimentation.

17. To validate TRUTEK's in-house experimental results, TRUTEK contracted with Alexai Ermakov, Ph.D. to compare the electrostatic charges between BLUEWILLOW's NANOBIO product and TRUTEK's NasalGuard® products. His experiments showed not only that the NANOBIO product exhibited a surface electrostatic charge, but also that the orders of magnitude of the charges of the BLUEWILLOW and TRUTEK products were of the same order of magnitude. Dr. Ermakov's Report is attached hereto as Exhibit 3. For further verification, TRUTEK contracted with Electro-Tech Systems

("ETS") in Perkasie, Pennsylvania, to run additional experiments. ETS personnel applied BLUEWILLOW's NANOBIO product and TRUTEK's NasalGuard® product to pig skin swatches. Pig skin is very similar to human skin tissue. The ETS and Ermakov experiments yielded similar results. The NANOBIO product exhibited a surface electrostatic charge of the same order of magnitude as the NasalGuard® product. The ETS report is attached hereto as Exhibit 4.

18. On January 31, 2021, Keith Altman, a resident of the State of Michigan, ordered and paid for one unit of NanoBio Protect Nasal Antiseptic online from Amazon.com. The product was to be shipped by Amazon.com to his address in Michigan. Mr. Altman used his computer to place the order, and the computer is located in Michigan, and it was located therein at the time that he placed his order. On February 1, 2021, Mr. Altman received the ordered one unit of NanoBio Protect Nasal Antiseptic in Michigan at the designated Michigan shipping address. A declaration of Keith Altman attesting to these events is attached hereto as Exhibit 5.

19. The ability to lessen the reactions to airborne contaminants by creating an electrostatic charge around a person's nasal passages was disclosed in TRUTEK's '488, '481, '005, and '802 Patents. A copy of the '802 Patent is attached hereto as Exhibit 6.

20. The ability to lessen the reactions to airborne contaminants by creating an electrostatic charge around a person's nasal passages is inherent in TRUTEK's formulations and manufacturing processes. Efficacy studies show that TRUTEK's methodology presented a viable solution to relief of allergy, cold, and flu symptoms.

21. Upon information and belief, just as TRUTEK's products work on allergens

and viruses by creating an electrostatic charge around nasal passages and further inactivate said allergens and viruses, the NANOBIO products work the same way.

22. At some point after this lawsuit was filed, BLUEWILLOW discontinued sales of the NANOBIO products, and the product descriptions were removed from BLUEWILOW'S website.

23. The NANOBIO products are sold to customers by Amazon.com as are TRUTEK's competing products also sold thereby. The competitive sales of the competing NANOBIO products deprive TRUTEK of sales and profits from its own products.

24. Upon information and belief, Defendants Robin Roe 1 through 10 and ABC Corporations 1 through 10 also infringe on the claims of TRUTEK's '802 Patent.

BLUEWILLOW'S Vaccine Products

25. BLUEWILLOW'S website reference to NANOBIO stated, "[t]he unique protectiveness of Nanobio® Protect is derived from Bluewillow's patented nanotechnology. (*See* Exhibit 1, second page.) No patent numbers were marked on NANOBIO's packaging.

26. According to information and belief, the NANOBIO droplets referred to in Exhibits 1 and 2 are nanoemulsion nanodroplets.

27. A nanoemulsion is an oil-in-water emulsion exitsing in extremely small nanodroplets that are less than 1,000 nanometers in size.

28. According to information and belief, BLUEWILLOW owns all of the intellectual property assets of Nanobio Corporation.

29. The following is a non-exclusive list of United States patents that are assigned

to Nanobio Corporation:

a. U.S. Patent No. 8,226,965 B2, issued on July 24, 2012 to James R. Baker, Jr., *et.al.*, entitled, "Methods of Treating Fungal, Yeast And Mold Infections."

b. U.S. Patent No. 8,703,164 B2, issued on April 22, 2014 to Ted C. Annis, *et.al.*, entitled, "Compositions For Inactivating Pathogenic Microorganisms, Methods of Making, the Compositions, and Methods of Use Thereof.

c. U.S. Patent No. 9,131,680 B2, issued on September 15, 2015 to Theodore C. Annis, *et.al.*, entitled, "Compositions For Inactivating Pathogenic Microorganisms, Methods of Making, the Compositions, and Methods of Use Thereof.

d. U.S. Patent No. 9,144,606 B2, issued on September 29, 2015 to James R. Baker, Jr., *et.al.*, entitled, "Nanoemulsion Influenza Vaccine."

e. U.S. Patent No. 9,492,525 B2, issued on November 15, 2016 to Ali I. Fattom, *et.al.*, entitled, "Human Respiratory Syncytial Virus Vaccine."

f. U.S. Patent No. 9,561,271 B2, issued on February 7, 2017 to Ali. I. Fattom, *et.al.*, entitled, "Nanoemulsion Respiratory Syncytial Virus (RSV) Subunit Vaccine."

g. U.S. Patent No. 10,206,996 B2, issued on February 19, 2019 to Ali. I. Fattom, *et.al.*, entitled, "Herpes Simplex virus Nanoemulsion Vaccine."

h. U.S. Patent No. 10,525,121 B2, issued on January 7, 2020 to Tarek Hamouda, *et.al.*, entitled, "Nanoemulsion Influenza Vaccine."

i. U.S. Patent No. 10,596,251 B2, issued on March 24, 2020 to Ali I. Fattom, *et.al.*, entitled, "Nanoemulsion Respiratory Syncytial Virus (RSV) Subunit Vaccine."

30. All of the patents listed above disclose and claim vaccines that are administered nasally and that are contained in or comprise nanoemulsions.

31. The following is a non-exclusive list of United States patents assigned to the Regents of the University of Michigan (the "Univ. Michigan Patents"), the inventors of which are current professionals working for BLUEWILLOW:

a. U.S. Patent No. 7,314,624 B2 issued on January 1, 2008 to James R. Baker, *et.al.*, entitled, "Nanoemulsion Vaccines."

b. U.S. Patent No. 9,974,844 B2 issued on May 22, 2018 to Andrzej Myc, *et. al.*, entitled, "Cancer Vaccine Compositions and Methods of Using the Same."

c. U.S. Patent No. 10,138,279 issued on November 27, 2018 to James R. Baker, Jr., *et.al.*, entitled, "Compositions and Methods For *Bacillus Antracis* Vaccination."

32. All of the above listed Univ. Michigan Patents disclose and claim vaccines that are administered nasally and that are contained in or comprise nanoemulsions.

33. According to information and belief, work performed by current BLUEWILLOW professionals, which culminated in applications that ultimately issued as the above Univ. Michigan Patents, was performed while the inventors were engaged in research at the University of Michigan and before their involvement at Nanobio Corporation.

34. By their very nature, nanoemulsion droplets possess an electrostatic charge. The polarity of the electrostatic charge of any droplet is the same as for every other droplet. If this were not so, the droplets would coalesce into a single liquid, and they would no longer be distinct from each other. The patents listed above disclose nanoemulsion droplets the electrostatic charges of which

are cationic (*i.e.*, positively charged).

35. The nanoemulsion adjuvants disclosed in the patents listed above also contain biocidic agents. Among the biocidic agents disclosed in the patents for use in the nanoemulsion adjuvants is benzalkonium chloride. Benzalkonium chloride is also a cationic agent. Benzalkonium chloride is also referred to *supra* as "BZK."

36. According to information and belief, BLUEWILLOW is currently developing vaccines, and it has been doing so for a number of years.

37. According to information and belief, some or all of the BLUEWILLOW vaccines that utilize a proprietary technology platform that it calls NanoVax® NE01 Technology. According to information and belief, NanoVax® NE01 Technology utilizes an oil-in-water nanoemulsion adjuvant to enable intranasal vaccines for challenging diseases.

38. According to information and belief, BLUEWILLOW'S vaccines are intended to produce and immune response in subjects to certain diseases and conditions, and those diseases and conditions include, but are not limited to: (1) anthrax; (2) influenza; (3) COVID-19 and its variants; (4) RSV (Respiratory Syncytial Virus); (4) SARS; (5) sexually transmitted diseases; (6) environmental allergies; (7) food allergies; (8) peanut allergies; and (9) certain forms of cancer.

39. According to information and belief, all of the above listed BLUEWILLOW vaccines utilize nanoemulsions (and are therefore electrostatically charged), contain cationic and biocidic agents, and are intended to be administered to subjects nasally.

40. According to information and belief, some or all of the above listed BLUEWILLOW vaccines infringe at least claims 1 and 2 of Trutek's '802

Patent.

41. According to information and belief, development of a vaccine against *Bacillus Anthracis* (anthrax) is ongoing being funded in part by a grant from the United States Department of Defense. According to information and belief, this vaccine is currently undergoing phased trials to determine safety and efficacy.

42. According to information and belief, development of a vaccine against influenza virus is ongoing being funded in part by a grant from the United States National Institutes of Health (NIH). According to informatin and belief, this vaccine is currently undergoing phased trials to determine safety and efficacy.

43. According to information and belief, BLUEWILLOW is collaborating with third parties in its vaccine development effort.

44. According to information and belief, BLUEWILLOW has not yet realized revenue from sales of its vaccine products.

GENERAL ALLEGATIONS

45. Plaintiff incorporates all of the above Paragraphs *supra* as though fully restated herein.

46. Plaintiff owns intellectual property related to certain formulations based upon attracting and/or repelling electrostatically charged particles in and around a person's nasal passages by application of a product that maintains an electrostatic charge on the skin or mucous membranes. Plaintiff has expended considerable resources to inventing, formulating, and developing its inventions and products and to protecting its rights therein. Plaintiff holds all rights, title, and interest to its '488, '481, '005, and '802 Patents. The '802

Patent is in full force and effect. TRUTEK is the legal owner of the '802 Patent and possesses all rights of recovery under the patent.

STATEMENT OF CLAIMS

COUNT 1

Infringement of the '802 Patent

47. Plaintiff incorporates all of the above Paragraphs *supra* as though fully restated herein.

48. Plaintiff owns intellectual property relating to an electrostatically charged multi-acting nasal application product and method covered by the '802 patent.

49. Defendants make, use, and intend to sell infringing products, *i.e.*, the BLUEWILLOW vaccines (listed *supra*), which infringe on the '802 Patent, without authority or license from Plaintiff.

50. Defendants infringe at least claims 1 and 2 of the '802 Patent because the BLUEWILLOW vaccines possess an electrostatic charge when applied to a person's nasal passages, and they contain a cationic agent and a biocidic agent.

51. Plaintiff has been damaged as a result of Defendants' infringement of the '802 Patent, and will continue to be damaged unless such infringement is enjoined by this Court pursuant to 35 U.S.C. § 283.

52. Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to damages adequate to compensate in an amount not less than a fair and reasonable royalty.

53. Alternatively, Plaintiff is entitled to a judgment from the Court, which enjoins sales or commercialization by BLUEWILLOW of its vaccines until after expiration of the '802 Patent.

COUNT 2

Infringement of the '802 Patent

54. Plaintiff incorporates all of the above Paragraphs *supra* as though fully restated herein.

55. Plaintiff owns intellectual property relating to an electrostatically charged multi-acting nasal application product and method covered by the '802 patent.

56. Defendants distributed, made, used, offered to sell and/or sold infringing products, *i.e.*, the NANOBIO products.

57. Defendants distributed, made, used, offered to sell and/or sold infringing products, *i.e.*, the NANOBIO products, which infringe on the '802 Patent, without authority or license from Plaintiff.

58. Defendants infringe at least claims 1, 2, 6, and 7 of the '802 Patent because the NANOBIO products possess an electrostatic charge when applied to a person's nasal passages, and they use benzalkonium chloride as a cationic agend and also as a biocidic agent.

59. Plaintiff has been damaged as a result of Defendants' infringement of the '802 Patent, and will continue to be damaged unless such infringement is enjoined by this Court pursuant to 35 U.S.C. § 283.

60. Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to damages adequate to compensate in an amount not less than a fair and reasonable royalty.

61. Alternatively, as the NANOBIO products are no longer being sold by Defendant, Plaintiff is entitled to damages adequate to compensate in an amount not less than the profits realized by Defendant for past sales of the NANOBIO products.

62. Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to damages adequate to compensate in an amount not less than a fair and reasonable royalty.

63. Plaintiff is entitled to a judgment from the Court, which enjoins sales or commercialization by BLUEWILLOW of its NANOBIO products until after expiration of the '802 Patent.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays that:

1. Defendants be required to pay over and account to Plaintiff for all gains, profits, and advantages derived from the infringement of its '802 Patent beginning April 24, 2012, based upon manufacture, sales, and/or use of the NANOBIO products in the United States and anywhere in the world, or by way of international commerce with the United States.
2. Defendants be enjoined from manufacturing and/or selling the NANOBIO products in the United States, either directly or indirectly.
3. Defendants be enjoined from actively inducing others to sell the NANOBIO products in the United States, either directly or indirectly.
4. Defendants be enjoined from exporting the NANOBIO products from the United States, either directly or indirectly.
5. Defendants be enjoined from manufacturing and/or selling the BLUEWILLOW vaccines until after expiration of the '802 Patent.
6. Defendants be enjoined from actively inducing others to sell the BLUEWILLOW vaccines until after expiration of the '802 Patent.
7. Defendants be enjoined from exporting the BLUEWILLOW vaccines until after expiration of the '802 Patent.
8. Plaintiff prays for such other and further relief as the Court may deem to be just and proper.

DEMAND FOR DISCOVERY OF INSURANCE COVERAGE

Pursuant to Defendants' discovery obligations, demand is made that all Defendants disclose to the Plaintiff whether or not there are any insurance agreements or policies under which any person or firm carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in this action or indemnify or reimburse for payments made to satisfy the judgment and provide Plaintiff with true copies of those insurance agreements or policies, including, but not limited to, any and all declarations sheets. This demand shall include and cover not only primary coverage, but also any and all excess, catastrophe and umbrella policies.

DEMAND FOR A JURY TRIAL

Plaintiff hereby demands a trial by jury of all issues triable of right by a jury in this action.

Dated: May 11, 2022

Respectfully Submitted,

Keith Altman, Esq.
Law Office of Keith Altman
33228 West 12 Mile Road, Suite 375
Farmington Hills, Michigan 48334
Telephone: (248) 987-8929
keithaltman@kaltmanlaw.com
Attorneys for Plaintiff

/s/ Stanley H. Kermen_____
Stanley H. Kermen, Esq.
4 Lenape Lane
East Brunswick, NJ 08816
(732) 593-7294 Tel.
(732) 312-5218 Fax
shk@shk-dplc.com
shklaw@kremen.us
Attorneys for Plaintiff

EXHIBIT 1

BlueWillow Biologics

Bringing Nanoscience to Life

NanoBio® Protect Nasal Antiseptic Solution

NanoBio® Protect

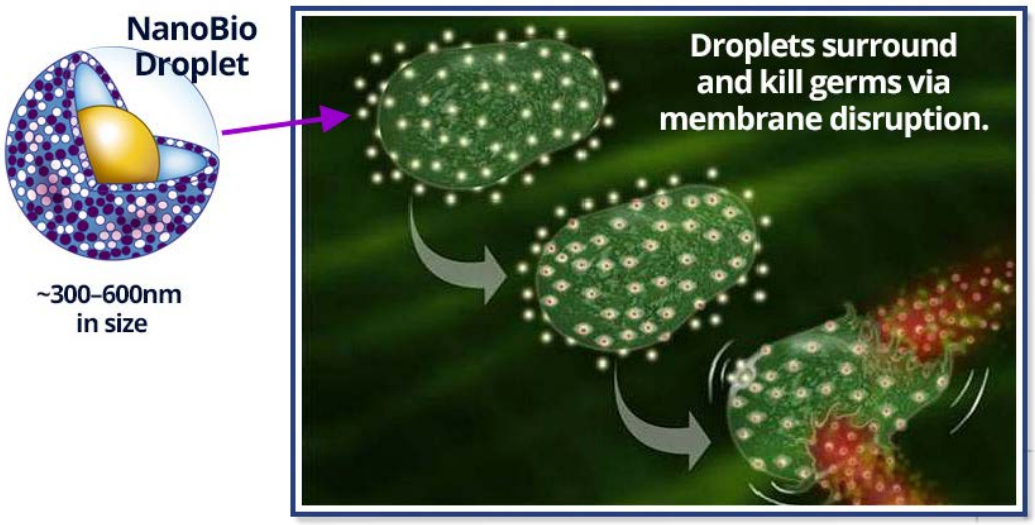
NanoBio® Protect is an alcohol-free nasal antiseptic solution that can be used to help reduce germs on skin that can cause infections. The product is easy to apply with any cotton swab for use on the skin around the rim of your nose as well as the skin up to one-half inch inside each nostril. It is non-irritating, fragrance-free and leaves no residue after application.

NanoBio® Protect is an FDA regulated over-the-counter skin antiseptic that incorporates the active ingredient benzalkonium chloride (BZK), which has been used in humans as a topical skin antiseptic since the 1940's. NanoBio® Protect is similar in concept to a hand sanitizer but is designed for use on the skin inside and around the nose where germs frequently enter the body.

The unique effectiveness of NanoBio® Protectis derived from BlueWillow's patented nanotechnology. NanoBio® Protect places the BZK antiseptic on the surface of nano-droplets, which results in at least four key advantages:

1. The nano-droplets are attracted to germs by electro-kinetic charge and present the BZK in such a way to enable killing of germs on contact,
2. The droplets persist on skin for 4 or more hours, enabling long-lasting effectiveness,
3. The droplets significantly hydrate skin to avoid dryness and cracking that can allow germs in.
4. And lastly, when bound to nano-droplets, BZK is non-irritating to the skin.

NanoBio® Protect kills germs via membrane disruption. NanoBio® Protect is comprised of positively charged droplets that are 300–600nm in size. The droplets are attracted to negatively charged germs in the skin. As shown to the right, the nano-droplets physically disrupt the outer membrane of germs, killing on contact.



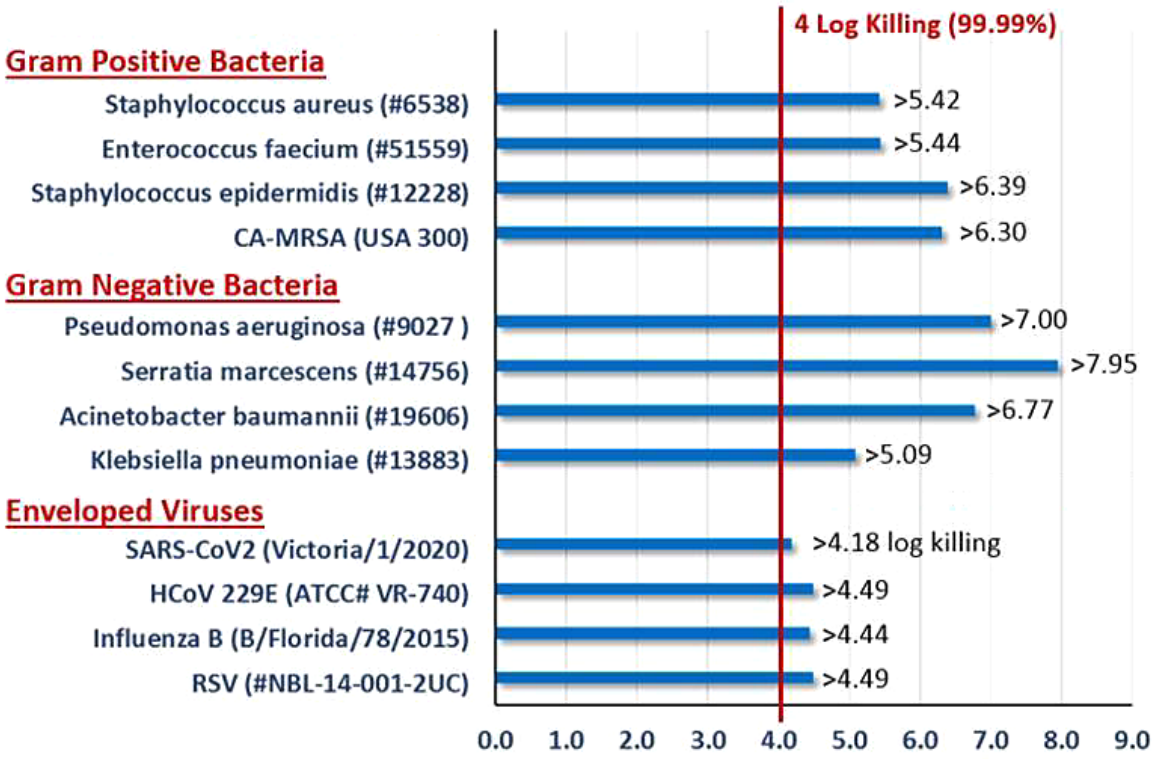
NanoBio® Protect is applied by thoroughly swabbing the skin up to one-half inch inside of each nostril and is recommended for use to help reduce germs on the skin in and around the nose that can cause infections. It should be used in conjunction with frequent handwashing, limited touching of the face, and social distancing to help minimize infection. Each 0.75 oz bottle of NanoBio® Protect will provide 40 or more treatments. A single application should involve the use of two swabs, including one for each nostril, or the use of a double-sided swab.

The product can be applied to the skin every 4–8 hours as needed, and is recommended for use during periods of increased risk of exposure to germs. For example, a healthcare worker might apply NanoBio® Protect two or more times a day. A flight attendant might apply the product 1–2 times during a long flight. Whereas, someone that is mostly staying at home in isolation may only need to apply it once a day or every few days prior to heading to the store or to an appointment.

Scientific Research Behind NanoBio® Protect

BlueWillow's nasal antiseptic

has not been clinically tested to confirm protection against COVID-19 infection in humans. It has



demonstrated both anti-bacterial and anti-viral activity in laboratory tests making it a potentially important additive measure to reduce the risk of infection

Standard *in vitro* lab experiments demonstrate that NanoBio® Protect kills more than 99.99% of germs within 60 seconds of exposure, as shown in the graph to the right.

Recent studies conducted by Public Health England also demonstrate NanoBio® Protect's ability to kill COVID-19 virus in laboratory tests. However, as stated above, studies to test for protection in humans have not yet been performed.

In addition, *ex vivo* tests in human skin (Figure A below) demonstrate that NanoBio® Protect persists on skin up to 7x better than commercial products and aqueous solutions containing the same BZK antiseptic agent. In vivo studies conducted in human volunteers (Figure B below) demonstrate that a single application of NanoBio® Protect significantly increases skin hydration for at least 3 hours, as compared to common hand sanitizer products:

Figure A

***Ex vivo* levels of BZK (µg/g tissue) in human abdominal skin following one application**
(dose of 100 µl/cm², measured at 24 hours)

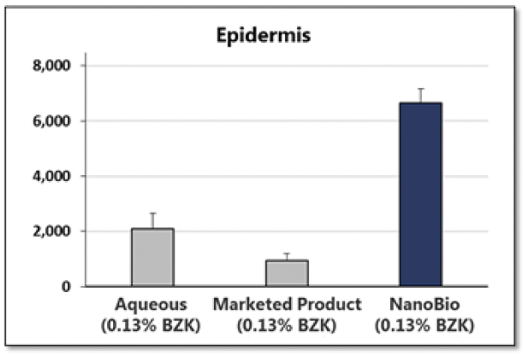
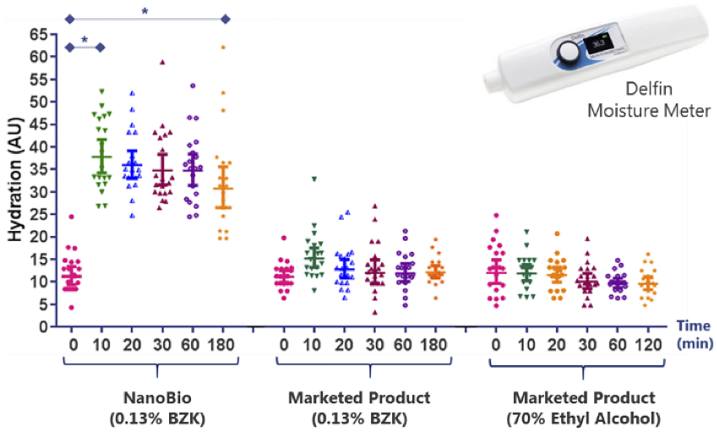


Figure B

Measured following 1mL application to the arms of human volunteers



Safety

NanoBio® Protect and similar NanoBio® formulations have been tested extensively in animal and human studies involving topical application to skin. These studies demonstrate that topical NanoBio® products are non-irritating and are not absorbed systemically. The products are alcohol-free and are comprised of nanodroplets that have been optimized to provide significant advantages when used as topical antiseptic products, without being absorbed through the skin and into the bloodstream.

NanoBio® Protect's active ingredient is 0.13% benzalkonium chloride, which is regulated by the FDA as a skin antiseptic and has been used in humans for over 75 years. Unlike alcohol-based products, NanoBio® Protect does not irritate or dry out the skin, and instead provides a moisturizing and comforting experience. The product should be applied with any cotton swab to the skin around the nose and up to one-half inch inside of each nostril where germs frequently enter the body.

Peer-Reviewed Scientific Publications

Other scientific publications describe the extensive research conducted with topical NanoBio formulations, as listed below:

- *"A Nanoemulsion as an Effective Treatment Against Human Pathogenic Fungi". Therapeutics and Prevention. 2019, Nov/Dec 4:6*
- *"Screening of Nanoemulsion Formulations and Identification of NB-201 as an Effective Topical Antimicrobial for Staphylococcus aureus in a Mouse Model of Infected Wounds". Military Medicine. 2016, May: 181, 5S:259-264*
- *"Nanoemulsion Therapy for Burn Wounds Is Effective as a Topical Antimicrobial Against Gram-Negative and Gram-Positive Bacteria". Burn Care Res. 2016, March /April: 37(2); 104-114*
- *"Treatment With a Novel Topical Nanoemulsion (NB-001) Speeds Time to Healing of Recurrent Cold Sores". Drugs Dermatol. 2012 Aug; 11(8):970-7*
- *"In Vitro Antibacterial Activity of NB-003 against Propionibacterium acnes". Antimicrobial Agents And Chemotherapy, Sept. 2011,Vol. 55, No. 9, p. 4211–4217*
- *"Topical Nanoemulsion Therapy Reduces Bacterial Wound Infection And Inflammation After Burn Injury". Surgery. 2010*
- *"NB-002, A Novel Nanoemulsion With Broad Antifungal Activity Against Dermatophytes, Other Filamentous Fungi, And Candida Albicans". Antimicrobial Agents And Chemotherapy, Aug. 2009, Vol. 53, No. 8, p. 3273–3279*
- *"In Vitro Activities of a Novel Nanoemulsion against Burkholderia and Other Multidrug-Resistant Cystic Fibrosis-Associated Bacterial Species". Antimicrobial Agents And Chemotherapy, Jan. 2009, Vol. 53, No. 1, p. 249–255*
- *"The Fungicidal Activity Of Novel Nanoemulsion (X8W60PC) Against Clinically Important Yeast And Filamentous Fungi". Mycopathologia 155: 195–201, 2001*
- *"A Novel Surfactant Nanoemulsion With A Unique Non-Irritant Topical Antimicrobial Activity Against Bacteria, Enveloped Viruses And Fungi". Microbiol. Res. (200I) 156, I-7*
- *"Inactivation Of Ebola Virus With A Surfactant Nanoemulsion". Acta Tropica 87 (2003) 315/320*
- *"Antimicrobial Mechanism Of Action Of Surfactant Lipid Preparations In Enteric Gram-Negative Bacilli". Journal of Applied Microbiology 2000, 89, 397-403*
- *"Prevention of Murine Influenza A Virus Pneumonitis by Surfactant Nano-emulsions". Antiviral Chemistry & Chemotherapy, 2000, 11:41-49*
- *"A Novel Surfactant Nanoemulsion with Broad-Spectrum Sporicidal Activity Against Bacillus Species". The Journal of Infectious Diseases, 1999, 180:1939–49*

BlueWillow Biologics

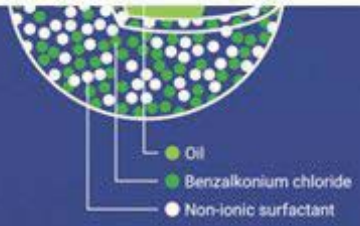
2311 Green Road | Ann Arbor, Michigan 48105

Telephone: 734-302-4000 | Fax: 734-302-9150

EXHIBIT 2

Protect

About How it Works Where to Buy FAQs Contact Us BUY NOW



earn more about
NanoBio Protect

NanoBio® Protect uses proprietary nanotechnology to deliver a common skin antiseptic in a new way. Learn more about the research behind NanoBio Protect

How is nanotechnology used in NanoBio Protect?

NanoBio Protect works because of its patented nano-formulation. The product's unique, oil-based nanodroplets enhance the antiseptic's antimicrobial activity, optimizing its ability to kill germs on the skin. The nanodroplets are small enough to be effective on the skin, but too large to be absorbed into the bloodstream — creating a layer of lasting protection.

NanoBio Protect adds BZK antiseptic to the surface of nanodroplets. This technology offers four distinct advantages over conventional BZK antiseptics:

- The Nanodroplets optimize the ability of the antiseptic to kill germs.
- The droplets sit on skin after application, enabling protection for up to 8 hours (in lab testing).
- Dry skin allows germs to penetrate. Nanodroplets hydrate the skin, preventing dryness and cracking.
- When bound to the oil-based Nanodroplets, the antiseptic does not irritate the skin.

- When bound to the oil-based Nanodroplets, the antiseptic does not irritate the skin.

Can you provide more detail on how the nano-technology works?

NanoBio Protect is composed of positively-charged droplets that are 300-600nm in size. These droplets are attracted to negatively-charged germs on the skin. The nanodroplets deliver the antiseptic BZK to the surface of the germs where the germ is inactivated via membrane disruption.

Other conventional BZK antiseptics often combine BZK with water, causing crystallization. When crystallization occurs, it rapidly inactivates the antiseptic and can lead to skin irritation. But because each NanoBio Protect droplet carries a positive charge, the droplets repel each other — keeping the BZK molecules separated and preventing crystallization.

Is nano-technology as used in this product safe?

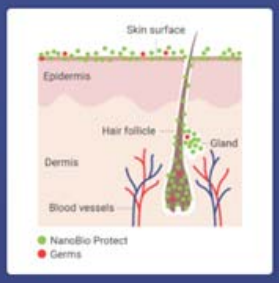
NanoBio® Protect uses proprietary nanotechnology to deliver a common skin antiseptic in a new way.

Effectiveness

The nanodroplets are optimized for size and charge in order to maximize their germ-killing impact. The positively-charged droplets deliver the antiseptic to the negatively-charged germs on the skin, inactivating them via membrane disruption.

Duration

NanoBio Protect's nanodroplets are positively charged, enabling them to stay active on the surface of the skin for significantly longer than common water-based BZK antiseptic solutions.



Safety

NanoBio Protect's nanodroplets are small enough to reach germs that hide in the deep layers of skin, but big enough to prevent absorption through the skin into the bloodstream.

EXHIBIT 3

Determination of Surface Electrostatic Charge on Nasal Application Test Products
Test Conducted and Report Prepared by Alexei Ermakov; Ph. D. (Physics), Sr. Consultant

I. TEST OBJECTIVE

The purpose of this test was to determine the magnitude (amount) of the surface electrostatic charge created by means of application of solution, serum, and spray containing permanently ionized molecules.

II. APPARATUS SETUP

The apparatus used in this electrostatic charge measurement of three nasal products comprised of a metal box containing a test sample spinner and a sensing electrode, which was connected to a Keithley Instruments 823 nano-volt amplifier (Figure 1).

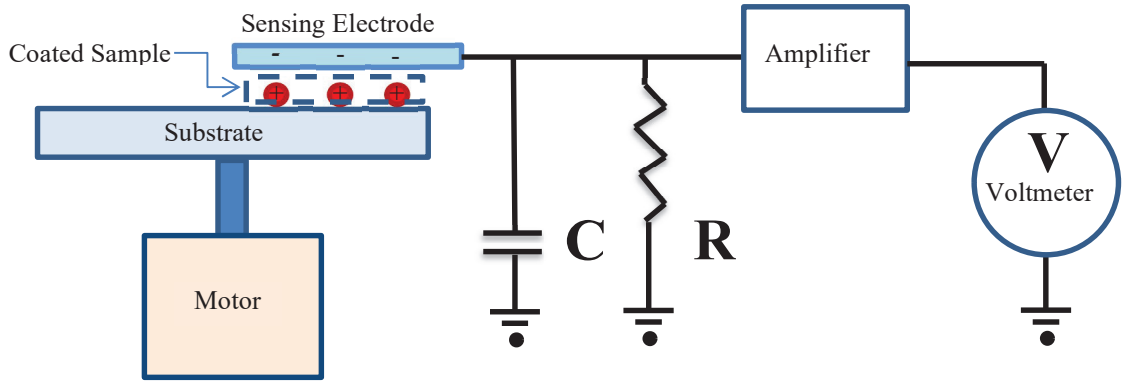


Figure 1
(Not to scale)

In Figure 1, C and R indicate the capacitance and resistance of the input circuitry of the amplifier respectively. Input capacitance was measured to be 80 pF and input resistance was 50 MΩ.

The spinner box and the sensing electrode apparatus are shown in Figure 2.

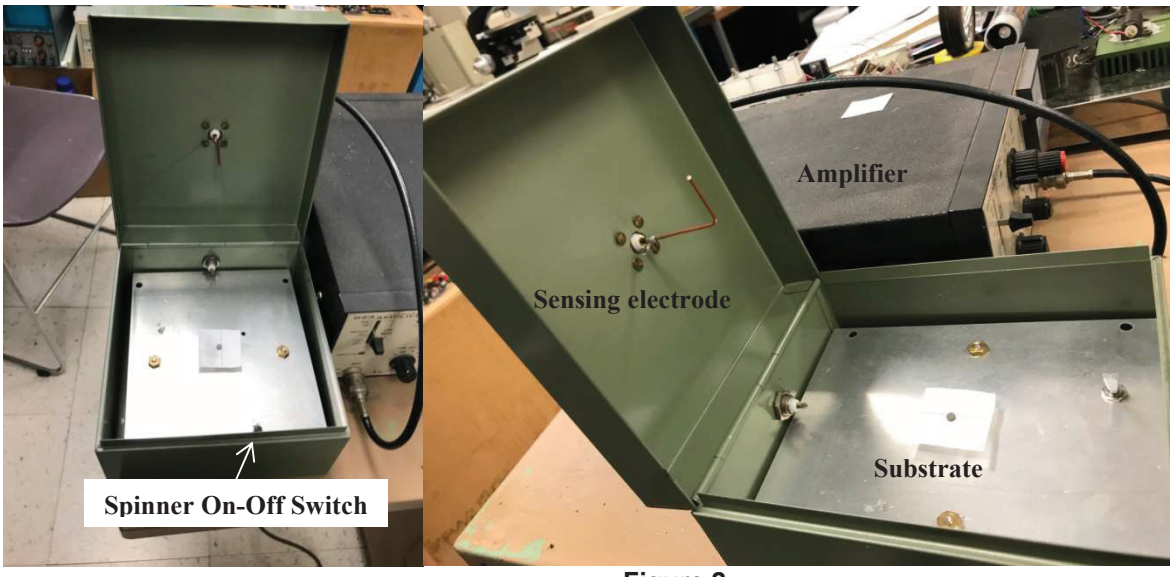


Figure 2

The sensing electrode is made of 1.3 mm diameter copper wire. When the metal box top is in the closed position, the sensing electrode is about 1.5 mm above the sample surface.

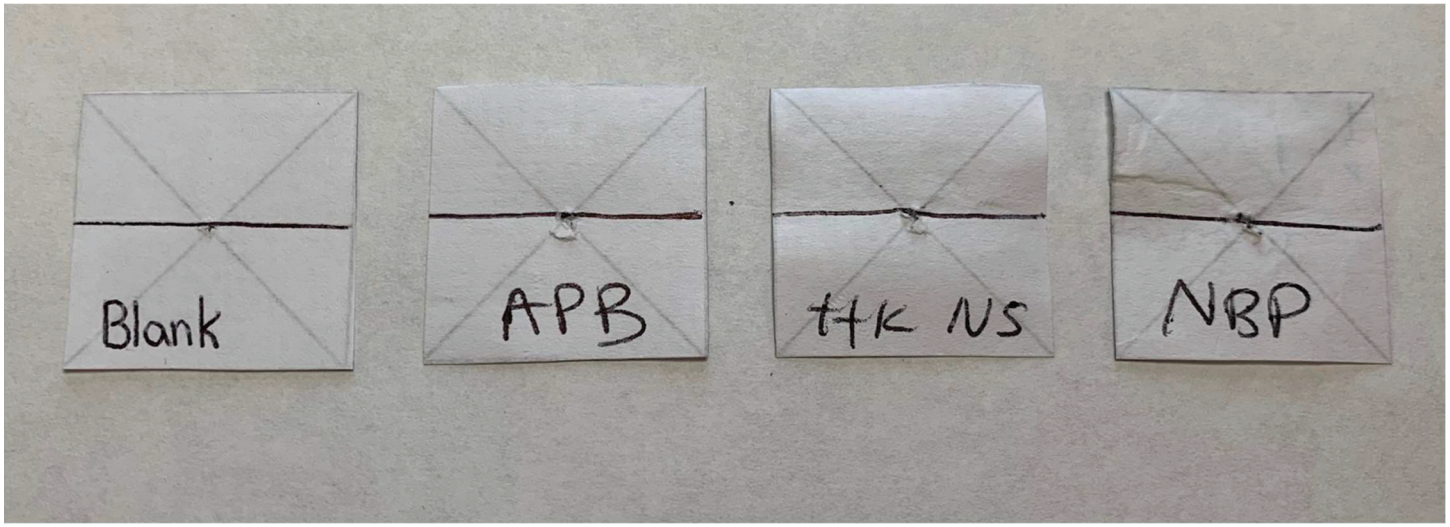
III. METHOD

Using the above mentioned apparatus, the amount of surface charge can be determined by means of measurement of induced image charges in the sensing electrode. The polarity of charge, i.e. cationic or anionic, was not the objective of this test measurement.

For each of the three nasal test products, a plain sheet of identical printer paper was used as a substrate. Each of these samples was prepared by coating the test product on 1-inch square substrate by a product under test. Three samples for each item/product were tested identically, an average calculated and recorded. Four items tested are shown in the Figure 3 below:

Product Test Samples:

1. Blank / Uncoated Substrate
2. TTK-APB / NasalGuard Airborne Particle Blocker (Gel)
3. TTK-NS / NasalGuard Misting Spray (Nasal Spray)
4. BW-NBP / Blue Willow NanoBio Protect (Solution for applications by a swab)



1. Blank	*2. TTK-APB*	*3. TTK-NS*	*4. BW-NBP*
Uncoated Substrate	*NasalGuard Airborne Particle Blocker (Gel)*	*NasalGuard Misting Spray (Nasal Spray)*	*Blue Willow NanoBio Protect (Solution)*

Figure 3 – Samples which were used in test conducted on December 22, 2020

Forceps were used every time each sample was placed onto and removed from the spinner. Each sample was carefully placed onto the spinner and the motor was switched 'On'. The metal box is then closed in order for the spinning sample to be within close distance (1.5 mm) below the copper sensing electrode.

During the sample spinning, treated and untreated surface repeatedly moved under the sensing electrode and the induced image creates an AC electrical current in the circuitry connected to the sensing electrode of the apparatus. The induced current is measured and is proportional to the surface electrostatic charge.

IV. TEST RESULTS

The surface charge was calculated using the following formula:

$$Q=V*C/A$$

Where Q is charge per unit area, V is measured voltage on the sensing electrode, C is capacitance and A is the area of the sample under the sensing electrode.

The measured surface charges for the tested products are:

Product / Trade Name	V Output (*) Volts	Amp Gain	V Electrode Volts	Charge Coulomb/in. sq. +/- (*)
Blank (Uncoated Substrate)	0.7 +/- 0.10	100,000	7.0E-06	7.0E-15 +/- 3.0E-16
	0.7 +/- 0.10	100,000	7.0E-06	7.0E-15 +/- 3.0E-16
	0.6 +/- 0.10	100,000	6.0E-06	6.0E-15 +/- 3.0E-16
Avg.	**0.7 +/- 0.10**	**100,000**	**7.0E-06**	**6.67E-15 +/- 3.0E-16**
NasalGuard Airborne Particle Blocker (Gel) TTK-APB	1.1 +/- 0.10	10,000	1.1E-04	8.80E-14 +/- 3.0E-15
	0.72 +/- 0.10	10,000	7.2E-05	5.76E-14 +/- 3.0E-15
	1.3 +/- 0.10	10,000	1.3E-04	1.04E-13 +/- 3.0E-15
Avg.	**1.04 +/- 0.10**	**10,000**	1.0E-04	**8.32E-14 +/- 3.0E-15**
NasalGuard Misting Spray (Nasal Spray) TTK-NS	1.12 +/- 0.10	10,000	1.12E-04	8.96E-14 +/- 3.0E-15
	0.9 +/- 0.10	10,000	9.0E-05	7.20E-14 +/- 3.0E-15
	0.675 +/- 0.10	10,000	6.75E-05	5.40E-14 +/- 3.0E-15
Avg.	0.90 +/- 0.10	**10,000**	**9.0E-05**	**7.19E-14** +/- 3.0E-15
Blue Willow NanoBio Protect (Solution) BW-NBP	0.07 +/- 0.10	10,000	7.0E-05	5.60E-14 +/- 3.0E-15
	0.58 +/- 0.10	10,000	5.8E-05	4.64E-14 +/- 3.0E-15
	0.35 +/- 0.10	10,000	3.5E-05	2.80E-14 +/- 3.0E-15
Avg.	**0.54 +/- 0.10**	**10,000**	**5.4E-05**	**4.35E-14** +/- 3.0E-15

(*) Indicates the approximate uncertainty of the value indicated in the column.

V. CONCLUSION

1) The test products i.e., Blank, NasalGuard Airborne Particle Blocker Gel, NasalGuard Misting Spray, and NanoBio Protect Solution, all demonstrated the presence of a surface electrostatic charge.

2) The surface electrostatic charge measured was determined to be approximately (in order of magnitude) similar in all three product samples tested.

Signatures:

(Alexei Ermakov)

EXHIBIT 4

SURFACE ELECTROSTATIC CHARGE EVALUATION OF NASAL APPLICATION PRODUCTS

Technical Report

Report Number (Test Order):	337A
Report Version:	1
Report issue Date	January 18, 2021
Customer Name:	Trutek Corp.
Purchase Order:	ETS01-21
Sample Types:	As indicated within
Commercial/Military Requirement:	None, N/A
Test Performed by:	Shane Burns
Signature:	Shane Burns
Report Reviewed by:	Troy Anthony
Signature:	

Report Revision History

Date	Report Version	Author	Comment
01/18/2021	1	Shane Burns	Original Release

I. TEST OBJECTIVE

The purpose of this test was to determine the magnitude (amount) of surface electrostatic charge created by means of the application of solution and spray containing permanently ionized molecules.

II. TEST EQUIPMENT INFORMATION

The ETS Model 230 Nanocoulomb Meter is a battery powered instrument for measuring charge directly in nanoCoulombs (nC) when connected with ETS Model 231 – Faraday Cup.

In its lowest range setting, Model 230 can accurately measure electrostatic charge as low as 0.01nC @ 20 nC range.

After placing the product test sample into the Faraday Cup (Model 231), Model 230 nanocoulomb meter digital display indicates the electrostatic charge.

Instrument(s)	Specification
Description	Precision Nanocoulomb Meter
Brand	Electro-Tech Systems
Model	230
Serial number	Lab unit
Last calibration date	04/02/2020

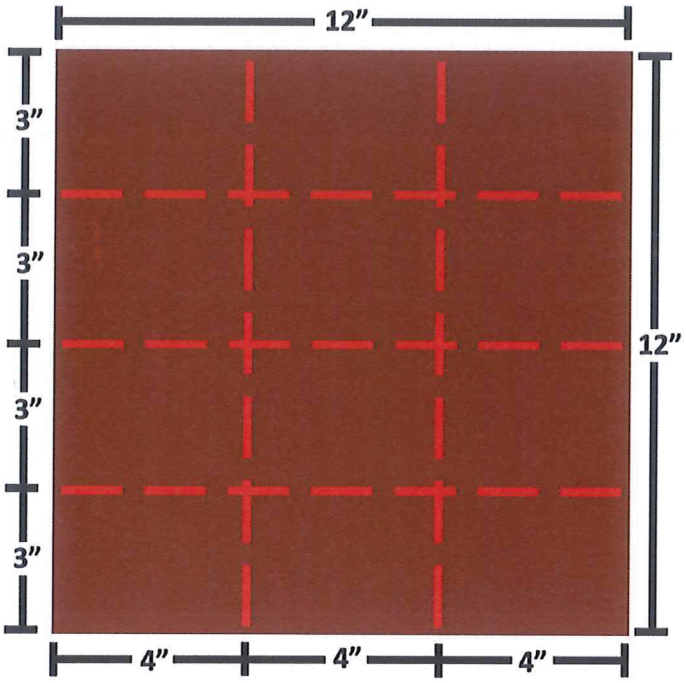
Model 230 – Nanocoulomb Meter

Instrument(s)	Specification
Description	Faraday Cup, Inner cup dia.: 3.1" x 4.0" High
Brand	Electro-Tech Systems
Model	231
Serial number	Lab unit
Last calibration date	04/02/2020

Model 231 – Faraday Cup
Inner Cup Dia.: 3.1" dia. 4" H (80 x 102mm)
Overall Dimensions: 4" dia. 6" H (102 x 152mm)

III. SUBSTRATE PREP

Real Pig Skin 12" x 12" was cut into 12 pieces of 4" x 3".



Each product test sample created was 4" x 3" rectangular uniformly coated with test product. After coating, test product was shaped into a circular cylinder of approximately 2" diameter x 3" high suitable for placing appropriately in Faraday cup (Model 231).

Total surface area of coated sample = 4" x 3" = 12 sq. inches = 12 sq. in x 2.54^2 $cm^2/inch^2$ = 77.42 sq. cm.

All Testing was performed at controlled temperature of 72.0 ±2 degrees F, and 12% ± 2% Relative Humidity (RH) in the environmental room.

IV. METHODOLOGY

i. The test substrates were ionized with Simco Model No. Aerostat XC, Serial No. R125608 to neutralize existing charge and measured repeatedly to see how much the substrate material (real pig skin) would affect the result.

ii. Before applying any test product sample, the substrate was neutralized again. This ensured that the substrate would not affect the measurement and the same base value is used.

iii. Each solution and spray test product was coated utilizing a cotton swab with approximately 1.5 ml (1.0 ml minimum to 2.0 ml maximum measured by use of a

pipette) for a smooth and uniform application on to [three] substrate sample-pieces (real pig skin) utilizing different cotton swabs for different type of test product.

iv. After waiting for 4 minutes (3 to 5 minutes) upon coating, while it was still moist, the coated substrates were placed in a Model 231 Faraday cup to accurately measure the charge of the coated product amount. Total electrostatic charge was measured in nC by ETS Model 230 as indicated on its digital display scale.

Product test samples:
1. TTK-NS; NasalGuard Misting Spray (Nasal Spray)
2. BW-NBP; BlueWillow NanoBio Protect (Solution)

V. TESTING

No.	Product	Total Surface Electrostatic Charge (nC/±)			
		Experiment 1	Experiment 2	Experiment 3	**Average**
1	TTK-NS	0.24	0.27	0.24	0.25
2	BW-NBP	0.85	0.09	0.35	0.43

*Note: Neutralized substrates' total electrostatic charge was measured at the beginning and at the end, (3) samples each, of the test. It was measured to have less than -0.07 nC in all cases, averaging only -0.023 nC.
It is, therefore, not a significant contributing factor to any charge measurements.

VI. DATA RESULTS

No.	Product	Charge Per Square (nC/sq. cm.)
1	TTK-NS	0.003
2	BW-NBP	0.006

Charge/sq. cm. = Average Total Charge ÷ 77.42

VII. CONCLUSIONS

1. The range of the total test product sample charge measured was as follows:

    i) TTK-NS; NasalGuard Misting Spray (Nasal Spray): Range was between 0.24 and 0.27 and, the average charge was 0.25 nC.

    ii) BW-NBP; BlueWillow NanoBio Protect (Solution): Range was between 0.09 and 0.85 and, the average charge was 0.43 nC.

2. The two test products i.e., NasalGuard Misting Spray (Nasal Spray) and BlueWillow NanoBio Protect (Solution) both demonstrated the presence of a surface electrostatic charge of similar order of magnitude.

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

Stanley H. Kremen,
Attorney at Law
4 Lenape Lane
East Brunswick, New Jersey 08816
(732) 593-7294
Attorney for the Plaintiff

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

CIVIL ACTION No. _____

DECLARATION OF KEITH ALTMAN

I, Keith Altman, being of full age, hereby depose and say under penalties of perjury according to the laws of the United States and the State of Michigan:

1. I am a resident of the State of Michigan.

2. On January 31, 2021, I ordered one unit of NanoBio Nasal Antiseptic online from Amazon.com using my computer, which is located in the State of Michigan. The Order Number is 112-1762892-7659450. The shipping address is 30474 Fox Club Drive, Farmington Hills, MI 48331-1956. Once my online order was completed and payment was made, I was informed that the product shipped the same day. A copy of the sales receipt and invoice is attached hereto as Exhibit A.

//

3. On February 1, 2021, I received the one unit of NanoBio Nasal Antiseptic that was apparently shipped to me from Amazon.com at the above address in Farmington Hills, Michigan.

I declare that the statements made by me above are true and that the exhibits attached hereto are genuine and are correctly described above. I understand that I am subject to the penalties of perjury for false representations according to the laws of the United States and the State of Michigan.

Keith Altman

EXHIBIT A

amazon.com

Final Details for Order #112-1762892-7659450

Order Placed: January 31, 2021
Amazon.com order number: 112-1762892-7659450
Order Total: $22.47

Shipped on January 31, 2021

Items Ordered	**Price**
1 of: *NanoBio Protect Nasal Antiseptic | Reduces the risk of respiratory infection | Kills 99.99% of Germs | 8 Hour Protection | Safe for Kids, Daily Use | Nasal Disinfectant | 40+ Uses | FSA/HSA eligible* Sold by: BlueWillow Biologics (seller profile) Condition: New	$21.20

Shipping Address:
Keith Altman
30474 FOX CLUB DR
FARMINGTON HILLS, MI 48331-1956
United States

Shipping Speed:
One-Day Shipping

Item(s) Subtotal:	$21.20
Shipping & Handling:	$0.00

Total before tax:	$21.20
Sales Tax:	$1.27

Total for This Shipment:	**$22.47**

Payment information

Payment Method:
Visa | Last digits: 3621

Billing address
Keith Altman
30474 FOX CLUB DR
FARMINGTON HILLS, MI 48331-1956
United States

Item(s) Subtotal:	$21.20
Shipping & Handling:	$0.00

Total before tax:	$21.20
Estimated Tax:	$1.27

Grand Total:	**$22.47**

FSA or HSA eligible — FSA or HSA eligible amount (includes taxes & shipping): $22.47

To view the status of your order, return to Order Summary .

EXHIBIT B


16.3G
NEW PATENTED NANOTECHNOLOGY
KILLS GERMS THAT ENTER THE NOSE
PROTECTS FOR 8 HOURS*
NEXT-LEVEL PROTECTION AGAINST INFECTION
NDC: 74315-001-02
NanoBioProtect
Nasal Antiseptic
• Kills 99.99% of Germs
• Alcohol-Free & Fragrance-Free
• Moisturizing & Soothing
40+TREATMENTS
0.61 FL OZ (18 mL)
EX2 2.2 Lbs 02/01 DDT6
30474 FOX CLUB DR
FARMINGTON HILLS , MI United
TBA153664056704
DDT6 CYCLE 1
CMH1 A DT6
PTKZ D DT6

EXHIBIT 6

US008163802B2

(12) **United States Patent**
Wahi

(10) **Patent No.: US 8,163,802 B2**
(45) **Date of Patent: Apr. 24, 2012**

(54) **ELECTROSTATICALLY CHARGED MULTI-ACTING NASAL APPLICATION, PRODUCT, AND METHOD**

(75) Inventor: **Ashok Wahi**, Hillsborough, NJ (US)

(73) Assignee: **Trutek Corp.**, Hillsborough, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 316 days.

(21) Appl. No.: **12/467,271**

(22) Filed: **May 16, 2009**

(65) **Prior Publication Data**

US 2010/0004337 A1 Jan. 7, 2010

Related U.S. Application Data

(60) Provisional application No. 61/085,855, filed on Aug. 3, 2008, provisional application No. 61/078,478, filed on Jul. 7, 2008.

(51) **Int. Cl.**
A61K 31/198 (2006.01)
A61K 31/14 (2006.01)

(52) **U.S. Cl.** **514/564**; 514/643

(58) **Field of Classification Search** 514/564, 514/643; 128/206.11
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

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2003/0223934	A1	12/2003	Wahi

Primary Examiner — Raymond Henley, III
(74) *Attorney, Agent, or Firm* — Stanley H. Kremen

(57) **ABSTRACT**

A product to reduce and method of reducing the risk of inhalation of harmful substances by applying a formulation composition to a substrate or the skin in close proximity of one or more nostrils. This formulation, when applied creates an electrostatic field having a charge. The electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate close to the skin and a biocidic agent renders microorganisms coming in contact the substrate or skin less harmful.

23 Claims, No Drawings

ELECTROSTATICALLY CHARGED MULTI-ACTING NASAL APPLICATION, PRODUCT, AND METHOD

CROSS REFERENCE TO RELATED APPLICATIONS

a) The Present application is the non-provisional counterpart of my pending U.S. Provisional Patent Application Ser. No. 61/085,555 (the '555 application) filed on Aug. 3, 2008 which is incorporated by reference in its entirety herein. The Present application claims the benefit of and priority to said '555 application.

b) The Present application is also the non-provisional counterpart of my pending U.S. Provisional Patent Application Ser. No. 61/078,478 (the '478 application) filed on Jul. 7, 2008 which is incorporated by reference in its entirety herein. The Present application claims the benefit of and priority to said '478 application.

c) The Present application is likewise related to my prior U.S. Provisional Patent Application Ser. No. 60/570,103 (the '103 application) filed on May 12, 2004 (now expired), and which is incorporated by reference in its entirety herein. The '478 application provides a virtually identical disclosure to the '103 application.

d) Furthermore, the Present application is related to my pending U.S. Provisional Application Ser. No. 61/078,472 filed on Jul. 7, 2008, which is incorporated by reference in its entirety herein.

e) The Present application is also related to my prior U.S. Provisional Patent Application Ser. No. 60/598,462 filed on Aug. 3, 2004 (now expired), and which is incorporated by reference in its entirety herein.

f) The Present application is additionally related to my U.S. Pat. No. 5,468,488, entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT AND METHOD" issued on Nov. 21, 1995. This patent is incorporated by reference in its entirety herein.

g) The Present application is further related to my U.S. Pat. No. 5,674,481, entitled "ELECTROSTATICALLY CHARGED NASAL TOPICAL APPLICATION PRODUCT" issued on Oct. 7, 1997. This patent is incorporated by reference in its entirety herein.

h) The Present application is moreover related to my U.S. Pat. No. 6,844,005 entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH" issued on Jan. 18, 2005. This patent is incorporated by reference in its entirety herein.

i) Finally, this application is furthermore related to US Non-Provisional Utility patent application Ser. No. 10/082,978 entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH" filed on Feb. 25, 2002. This patent application is incorporated by reference in its entirety herein.

FIELD OF THE INVENTION

The Present Invention relates to the field of protective compositions against assault by various irritants and noxious substances as well as against assault by assorted microorganisms that typically gain entry into the body through the airway and/or nasal mucosa. The Present Invention also relates to anti-viral, anti-bacterial, and anti-microbial products and methods that involve the use of products heretofore developed for restricting the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages. This reduced the inflow of airborne contaminants to the nasal passages by capturing the contaminants and keeping them from entering the body. In the present invention, these electrostatically charged nasal application products capture and hold the contaminants including viruses, bacteria, and other harmful microorganisms or toxic particulates, inactivate them dermally outside the body and render them harmless.

BACKGROUND OF THE INVENTION

The nasal passages and nasal mucosa serve as body entry points for a wide variety of noxious and toxic substances. The body's immune system responds with certain relatively harmless irritants to the nasal passages and airways with reflex responses such as coughing and sneezing. This merely reintroduces the irritants into the environment. However, when the irritant comprises microorganisms, especially those that reproduce within the body and that are transmitted by coughing and sneezing, others may become infected. When a person feels a cough or a sneeze coming on, he merely covers his nose and mouth. However, if that person is contagious, this action does little to prevent others from also becoming infected. Furthermore, the use of a tissue or handkerchief for this purpose is extremely inefficient. This limits the protection of an individual from becoming infected or infecting others.

Other means of dealing with preventing inhalation of harmful or irritating substances or of infections agents include wearing facemasks to filter out these irritants. An example of this is the simple dust mask, typically found in the hardware store or medical supply store. However, even these are inadequate and inefficient. In many localities, during flu season, one can see a large number of people wearing these dust masks in public places. The dust masks are now known to be ineffective. Another example of this preventative method is the gas mask, which is more efficient than the dust mask. Yet, even gas masks are not highly efficient with respect to microscopic and sub-microscopic microorganisms. Furthermore, they are extremely cumbersome and cannot generally be used during normal day-to-day activities.

Patents such as U.S. Pat. No. 6,844,005 describe electrostatically charged compositions that may be applied externally in the vicinity of the nostril and attract oppositely charged materials that would otherwise be inhaled. However, those compositions simply create an electrostatic field that helps to filter out oppositely charged materials. While this action may offer suitable protection against particles that are inhaled passively, they suffer from the fact that they cannot completely deal with particulates that have their own internal means of overcoming the electrostatic forces, such as microorganisms that are motile within the air stream. Furthermore, actions by the person having those electrostatic compositions in the vicinity of the nostrils can sufficiently displace the offending particles or organisms, especially in such instances as blowing or wiping the nose, so that particles that were held captive by the former compositions could become dislodged, again set free, and be inhaled.

OBJECTS OF THE INVENTION

It is therefore an object of the invention to provide a composition that can be readily applied to the exterior region around the nostril and/or slightly inside the edge of the nostril or near the vicinity of the source of release with method and compositions capable of capturing particulates and microorganisms.

It is another object of the invention to have the capability to hold it for a duration from being dislodged in to the air stream again.

It is a further object of the invention to provide a composition that can be applied near the vicinity of the source of release or to the area around the exterior of and/or slightly inside the edge of the nostril that will inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition.

It is yet another object of the invention to provide a composition that can be applied to a filter substrate for improving the substrates ability to trap and hold particulates and microorganisms and to simultaneously inactivate, kill, or render harmless the microorganisms so trapped. Such filter substrate could be placed in the close proximity of the skin near the path of inhalation, near the source of release of such particulates while the inhaler is at a distance or both.

It is still another object of the invention to provide a method of prophylactically preventing or of substantially reducing the risk of infection by an infectious agent without the utilization of ingested antiviral and/or antibacterial agents.

Yet other objects of the invention will be apparent to those of ordinary skill once having benefit of the instant disclosure. In all of the foregoing objects, the deficiencies of the previously mentioned prior art are overcome by the teachings of this invention.

SUMMARY OF THE INVENTION

These and other objects of the invention are unexpectedly achieved by an electrostatically charged composition having at least one polymeric quaternary compound in an aqueous or non-aqueous based formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to anti-microorganism, anti-viral/anti-bacterial products and methods that involve the use of products that restrict the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages. Additionally, in the present invention, these electrostatically charged nasal application products are used to hold the contaminants including micro-organisms, viruses, bacteria, and other harmful or toxic particulate outside the body and render them harmless.

Emergencies of Anthrax lead to the concept of avoidance of inhaling airborne microscopic and sub-microscopic contaminants. It is the intention of the Present Invention to filter and render harmless materials such as anthrax spores, human corona virus, smallpox virus, influenza virus, avian flu virus, swine flu virus, rhino virus, and other biological or chemical elements/toxins/irritants, and the like, prior to their entering the nasal passages.

Airborne microorganisms are a major cause of respiratory ailments in humans, causing allergies, asthma, and pathogenic infections of the respiratory tract. Airborne fungal spores are also important agents that spread diseases. Respiratory diseases cause many fatalities and are a cause of great concern. During a sneeze, millions of tiny droplets of water and mucus are expelled at a high velocity. The droplets contain viral particles and/or bacteria. This is a means of transmission of several diseases by inhaled airborne particles as follows:

VIRAL DISEASES (virus type in brackets)	BACTERIAL DISEASES (bacterial name in brackets)
Chickenpox (Varicella)	Whooping cough (*Bordetella pertussis*)
Flu (Influenza)	Meningitis (*Neisseria* species)
Measles (Rubeola)	Diphtheria (*Corynebacterium diphtheriae*)
German measles (Rubella)	Pneumonia (*Mycoplasma pneumoniae*, *Streptococcus* species)
Mumps (Mumps)	Tuberculosis (*Mycobacterium tuberculosis*)
Smallpox (Variola)	Anthrax (*Anthracsis* bacterium)
SARS (Human Corona)	

Diseases caused by environmental particulates include, but are not limited to the following:

ENVIRONMENTAL PARTICULATE DISEASES	SOURCE
Psittacosis (*Chlamydia psittaci*)	Dried, powdery droppings from infected birds (parrots, pigeons, etc.)
Legionnaire's disease (*Legionella pneumophila*)	Droplets from air-conditioning systems, water storage tanks, etc., where the bacterium grows.
Acute allergic alveolitis (various fungal and actinomycete spores)	Fungal or actinomycete spores from decomposing organic matter (composts, grain stores, hay, etc.)
Aspergillosis (*Aspergillus fumigatus*, *A. flavus*, *A. niger*)	Fungal spores inhaled from decomposing organic matter.
Histoplasmosis (*Histoplasma capsulatum*)	Spores of the fungus, in old, weathered bat or bird droppings.
Coccidioidomycosis (*Coccidioides immitis*)	Spores in air-blown dust in desert regions (Central, South and North America) where the fungus grows in the soil.

To accomplish the present invention, a formulation having at least one polyquaternary ammonium compound is prepared, such compounds, alone or together capable of creating an electrostatic field on and around a surface to which it is applied, including surfaces such as skin, textile (woven and non-woven), and hard surfaces, such as floors, walls, wood, metal, plastic, etc. The formulation is generally aqueous based, but may include non-aqueous solvents used which are compatible with the other formulation components and the application surface to which it is applied. Preferably, the formulation is an aqueous formulation. In addition to the polyquaternary ammonium compound, the composition includes at least. Furthermore, the composition may contain, but is not required to contain various thickeners, gellants, fragrances, colorants, emollients, humectants, and generally other suitable components that are compatible with the end use application and the other components of the formulations. Thus, a composition of the invention that is intended to be applied to a filter substrate that is perhaps used as a mask with an additional liner between a user and the filter substrate may utilize materials that would not be compatible with direct contact with skin, although it is preferable that all of the components are compatible with direct application to the skin as a means of limiting reaction due to inadvertent contact between the composition and the skin.

A formulation of the invention comprises:

water,

at least one quaternary thickener,

a preservative,
a conditioner,
an emulsifier,
a biocidic agent, and
a neutralizing agent added to adjust and achieve a pH in the range of 5.0 to 6.8.

It may further comprise without limitation a combination of the following:
a surfactant,
a thickener,
an emollient,
a humectant, and
a binder.

In an exemplary embodiment of such a formulation, a quaternary thickener may comprise without limitation, at least one of the following:
Polyquaternium-10
Polyquaternium-22
Polyquaternium-67
Polyquaternium-70
Polyquaternium-72
Polyquaternium-88
Cocodimonium Hydroxypropyl Hydrolyzed Keratin
Hydroxypropyltrimonium Wheat Protein

Benzalkonium Chloride may also serve the same function, but it is also a cationic agent as well as a biocide. Another biocide that may be used is Lysine HCL.

In an exemplary embodiment of such a formulation, an emulsifier may comprise without limitation, at least one of the following:
Cetyl Alcohol (which can also serve as a thickener)
Cetearyl Alcohol
Glyceryl Stearate
Ceteareth-20
PEG-40 Stearate
Dicetyl Phosphate
Ceteth-10 Phosphate

In an exemplary embodiment of such a formulation, the emollient may be Isocetyl Behenate without limitation. The thickener may be Cetyl Alcohol or Stearyl Alcohol without limitation.

In an exemplary embodiment of such a formulation, a preservative may comprise without limitation, at least one of the following:
Phenoxyethanol;
Methylparaben;
Butylparaben;
Ethylparaben;
Propylparaben;
Isobutylparaben.

Examples of typical formulations found to be effective appear in the ten tables that follow. Percentages are given by weight.

TABLE 1

Ingredient	Percent Range	Function
Water	62%-80%	Solvent, Moisturizer
Gluconolactone, Sodium Benzoate	1%	Preservative
Lysine HCL	1%	Conditioner
Polyquaternium - 67	3%-6%	Conditioner
Octoxynol - 9	2%-5%	Surfactant
Polyquaternium - 72	6%-10%	Conditioner
Polyquaternium - 70	0.5%-1%	Conditioner
Dipropylene Glycol Isocetyl Behenate	4%-6%	Emollient
Stearyl Alcohol	1%-3%	Thickener
Cetyl Alcohol	0.25%-1%	Thickener
Ceteareth - 20, PEG - 40 Stearate, Cetearyl Alcohol	1%-2%	Emulsifier
Water, Hydrolyzed Algin	0.5%-1.5%	Conditioner
Hydrolized Soy Protein	0.25%-1%	Conditioner

TABLE 2

Ingredient	Percent Range	Function
Water	72%-88%	Solvent, Moisturizer
Phenoxyethanol Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	3%-6%	Conditioner, Quaternary
Nonoxynol - 10	2%-4%	Surfactant
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Polyquaternium - 88	1%-4%	Conditioner, Quaternary
Cetearyl Alcohol, Glyceryl Stearate Emulsifier, PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Cetearyl Alcohol, Dicetyl Phosphate, Ceteth - 10 Phosphate	0.5%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.01%-0.05%	Neutralizing Agent

TABLE 3

Ingredient	Percent Range	Function
Water	67%-87%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	3%-7%	Conditioner, Quaternary
Polyquaternium - 72	3%-7%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolized Keratin	1%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-4%	Conditioner, Quaternary
Cetyl Alcohol	1.5%-2.5%	Thickener
Cetearyl Alcohol, Glyceryl PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.025%-.075%	Neutralizing Agent

TABLE 4

Ingredient	Percent Range	Function
Water	71%-83%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	4%-6%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternum - 88	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	2%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3.5%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.025%-.075%	Neutralizing Agent

TABLE 5

Ingredient	Percent Range	Function
Water	73%-85%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	2%-3%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	2%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.75%	Neutralizing Agent

TABLE 6

Ingredient	Percent Range	Function
Water	69%-85%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben,	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 10	0.25%-0.85%	Conditioner, Quaternary
Polyquaternium - 67	1.5%-3.5%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cetyl Alcohol	1%-3%	Thickener
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.75%	Neutralizing Agent

TABLE 7

Ingredient	Percent Range	Function
Water	67%-86%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-4%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-1.5%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolized Keratin	0.5%-1.5%	Conditioner, Quaternary
Microcare Quat CTC 30	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	3%-5%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 8

Ingredient	Percent Range	Function
Water	58%-74%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	10%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-3%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-1.5%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-1.5%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Polybutene	4%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide

TABLE 8-continued

Ingredient	Percent Range	Function
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.0.05%-0.1%	Neutralizing Agent

TABLE 9

Ingredient	Percent Range	Function
Water	54%-73%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	8%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-4%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Polybutene	3%-4%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 10

Ingredient	Percent Range	Function
Water	52%-71%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	9%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-3.5%	Conditioner, Quaternary
Polyquaternium - 67	1%-3%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Polybutene	5%-6%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 10-continued

Ingredient	Percent Range	Function
Wheat Protein		
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

All of the formulations described in TABLE 1-10 representing various embodiments of the Present Invention operate in the manner that was disclosed herein. The same results may be achieved by varying the percentages for the active and inactive ingredients. Varying the percentages for the active ingredients affects the potency of the formulation. Varying the percentages for the inactive ingredients affects the consistency of the formulation. The desired results may be achieved by varying the ingredients and their amounts by those skilled in the art without undue experimentation.

I claim:

1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:

a) electrostatically attracting the particulate matter to the thin film;

b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:

a) electrostatically attracts the particulate matter to the thin film;

b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivates the particulate matter and renders said particulate matter harmless.

3. The formulation of claim **2** wherein the at least one cationic agent is a polymeric quaternary ammonium compound.

4. The formulation of claim **3** wherein the at least one polymeric quaternary ammonium compound is taken from the group consisting of:

Polyquaternium-10,
Polyquaternium-22,
Polyquaternium-67,
Polyquaternium-70,
Polyquaternium-72, and
Polyquaternium-88.

5. The formulation of claim **2** wherein the at least one cationic agent is Cocodimonium Hydroxypropyl Hydrolyzed Keratin or Hydroxypropyltrimonium Wheat Protein.

6. The formulation of claim **2** wherein the at least one cationic agent is Benzalkonium Chloride.

7. The formulation of claim **2** wherein the at least one biocidic agent is Benzalkonium Chloride or Lysine HCL.

8. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising:

a) at least one biocidic agent, and

b) at least one quaternary thickener.

9. The formulation of claim **8** wherein the at least one biocidic agent is Benzalkonium Chloride or Lysine HCL.

10. The formulation of claim **8** wherein the at least one quaternary thickener is taken from the group consisting of:

Polyquaternium-10,
Polyquaternium-22,
Polyquaternium-67,
Polyquaternium-70,
Polyquaternium-72, and
Polyquaternium-88.

11. The formulation of claim **8** wherein the at least one cationic agent is Cocodimonium Hydroxypropyl Hydrolyzed Keratin or Hydroxypropyltrimonium Wheat Protein.

12. The formulation of claim **8** wherein the at least one cationic agent is Benzalkonium Chloride.

13. The formulation of claim **8** further comprising:

a) water,

b) a preservative,

c) a conditioner, and

d) an emulsifier.

14. The formulation of claim **13** further comprising a neutralizing agent added to adjust a pH in the range of 5.0 to 6.8.

15. The formulation of claim **13** further comprising a surfactant.

16. The formulation of claim **13** further comprising a thickener.

17. The formulation of claim **13** further comprising an emollient.

18. The formulation of claim **13** further comprising a humectant.

19. The formulation of claim **13** further comprising a binder.

20. The formulation of claim **13** wherein the preservative is taken from the group consisting of:

Phenoxyethanol,
Methylparaben,
Butylparaben,
Ethylparaben, and
Isobutylparaben.

21. The formulation of claim **13** wherein the emulsifier is taken from the group consisting of:

Cetyl Alcohol,
Cetearyl Alcohol,
Glyceryl Stearate,
Ceteareth-20,
PEG-40 Stearate,
Dicetyl Phosphate,
Ceteth-10 Phosphate.

22. The formulation of claim **16** wherein the thickener is Cetyl Alcohol or Stearyl Alcohol.

23. The formulation of claim **13** wherein:

a) the amount of water ranges from 54% to 90% by weight

b) the amount of the quaternary thickener ranges from 0.5% to 5.0% by weight,

c) the amount of biocidic agent ranges from 0.25% to 2% by weight,

d) the amount of emulsifier ranges from 0.5% to 4% by weight.

* * * * *